# BREAKOUT GROUP #4
# ETHICAL CONSIDERATIONS AND COMMUNITY PERSPECTIVES

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# TOPICS COVERED

- Regulatory and ethical framework
- Communication and messaging
- Informed consent process
- Ancillary care needs

# REGULATORY AND ETHICAL FRAMEWORK: 21 CFR 50, 45 CRF 46, SUBPART D

- Research involving children either
  - Must be restricted to "minimal risk" or a "minor increase over minimal risk" if there is no potential for direct benefit to the enrolled child

  or

  - If more than minimal risk, the risk must be justified by anticipated direct benefits to the child … the balance of which is at least as favorable as any available alternatives

***Who decides if these criteria are met?***

# WHO DECIDES?

- Regulatory authorities
- IRBs/ECs
- Communities
- Parents/guardians
- Participants

**At each level, adequate and appropriate information must be made available to enable an informed decision**

**There are "layers of trust" underlying the decisions made at each level.**

# WHO DECIDES?

- Regulatory authorities
- IRBs/ECs
- Communities
- Parents/guardians
- Participants

**Transparent decision-making must occur at all levels.**

**Wording related to potential benefits (or not) in protocols and informed consent forms should reflect these decisions.**

# WHO DECIDES?

- Regulatory authorities
- IRBs/ECs
- Communities
- Parents/guardians
- Participants

**As children age up, they have a right to be involved in informed decision-making about their own study participation.**

# COMMUNICATION AND MESSAGING

- Cure-related research presents significant information and education challenges
  - Cure versus remission; even remission is not well understood; **need for cross-cultural analogies** to explain the goals of cure-related research
  - "Hope for cure" even if understand there may be no benefit
  - Unknown safety and unproven efficacy of interventions
  - Unknown implications for participation in future research
  - Social and family impacts and burdens

# COMMUNICATION AND MESSAGING

- Establish a robust multi-level communication plan to implement throughout the study, and thereafter
- Build community empowerment by providing a foundation of knowledge about cure-related studies and diverse methods of disseminating this knowledge ("cure navigators")

# COMMUNICATION AND MESSAGING

- Messaging re: potential treatment interruption
  - Numerous audiences and stakeholders in addition to the participant and his or her immediate family
  - Explaining "what's different" for the participant in the study
  - Understanding each individual decision as unique to the individual context

# INFORMED CONSENT PROCESS

- Methods should be data driven and incorporate best practices
  - Adequate time
  - Family-friendly discussions, potentially with multiple different messengers
  - Educate about "why" and not just "what" (e.g., reason for intensive visit schedule)
  - Dialog not monolog

# INFORMED CONSENT PROCESS

- Incorporate best practices
  - Visual aids
  - Assessment of understanding
  - Reports from screened and enrolled participants
  - *Process continues throughout the study and thereafter*
  - *Peer support and problem solving*

# ANCILLARY CARE NEEDS

- Study team and sites should identify likely needs and establish plans to address these in partnership with non-study health systems prior to study initiation
- Study team should carefully consider the implications of planned evaluations that may identify ancillary care needs that cannot be readily addressed
- Study team should carefully consider and plan for post-study ancillary care needs

# REFERRAL TO NON-STUDY SOURCES OF ANCILLARY CARE

- Considerations of trust and rapport with study staff; potential stigma if referred by study staff; health care visit burdens and convenience
- Care for the study participant, care for the family
- Considerations for drug sharing: optimal for all to be receiving standard of care, with study intervention added for the study participant

# THANK YOU